EXHIBIT H

Polymer Science and Materials Chemistry

Exponent®

Expert Report of Dr. Steven MacLean

In the U.S. District Court for the Southern District of West Virginia, Charleston Division

This document relates to:

Pelvic Mesh Litigation

In re: Ethicon Inc., Pelvic Repair System Products Liability Litigation MDL 2327

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Seven Year Dog Study

Study Protocol

As part of the microcrack committee, Ethicon initiated a comprehensive 10-year *in vivo* study commencing in 1985. One of the primary motivations of this study was to assess the long-term effects, if any, of implantation on various suture materials. Ethicon selected PROLENE (polypropylene based), PVDF (polyvinylidene fluoride), ETHILON (nylon 6 and nylon 6,6), and Novafil (polybutester) monofilament 5-0 sutures to be examined in this study. Periodic evaluations were performed after two, five, and seven years *in vivo*, with baseline testing of unimplanted sutures also performed at each period. Each periodic evaluation consisted of generating mechanical and chemical property data as well as surface morphology micrographs to capture any physical changes in the candidate suture materials. In this study, twenty-four mature female Beagle dogs served as animal models (five animals per study period, plus four replacements in case of premature death). Each animal had sutures implanted in six different locations, and each implant location received a bundle of six sutures (with each bundle containing a single type of suture). A simplified schematic of the surgery sites is shown in Figure 6.

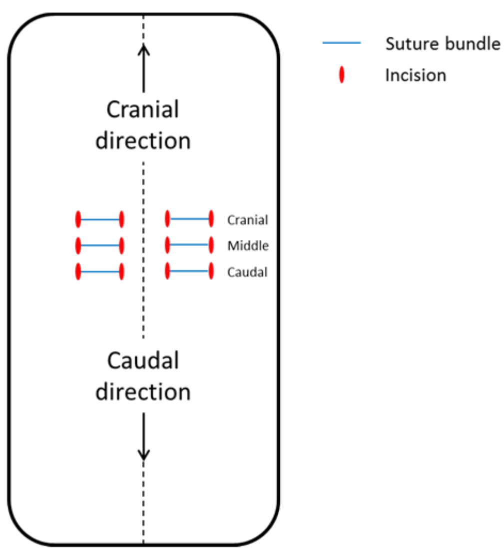

Figure 6. Simplified illustration of the ventral area of a dog torso, showing the location of the six suture implantation sites.

Five dogs were euthanized at each study period. For each suture type, one strand (selected at random) was immediately placed, without cleaning or being allowed to dry, into a test tube filled with sterilized deionized water to be examined and imaged with optical (OM), scanning electron (SEM), and infrared (IR) microscopy.

The remaining five strands were examined for surface damage, and then placed into saline-soaked towels in preparation for tensile testing, which was performed on the explanted strands of each suture type and ten non-implanted exemplars. After testing, the chemical groups present on the surfaces of the fragments were identified by FTIR, and the molecular weight was evaluated by inherent viscosity, and gel permeation chromatography (GPC).

Study Results

In this study, prior to additional testing and examination, FTIR spectra were taken on all explanted sutures to verify that they had been correctly identified during the explantation procedure.[90]

IR microscopy is a technique very similar to FTIR, albeit with smaller spatial resolution. This technique made it possible to compare the chemical groups present in cracked and non-cracked regions. After seven years *in vivo*, spectra for PROLENE sutures showed "a broadened weak absorbance at about 1650 cm^{-1}," Ethicon's scientists concluded that this was "possible evidence of slight oxidation."[90] The absorbance peak typically assigned to carbonyl containing functional groups in oxidized polypropylene is 1650-1810 cm^{-1}.[8,85,86] However, it is important to note that these samples were not cleaned, in fact tissue was still present on the surface of the suture and "cracking of the suture was seen through the tissue."[91] The existence of tissue, including tissue that may contain lipids or fatty acids, could readily account for the observed carbonyl functionality on the cracked surface of the suture; therefore, no scientific conclusions can be drawn by IR microscopy regarding the oxidation of PROLENE sutures. The spectra from cracked areas on ETHILON and Novafil sutures were not different than spectra obtained from uncracked areas. However, it was noted that absorbance frequencies related to oxidation "would

[90] Ethicon's Seven Year Dog Study (ETH.MESH.09888187) pg.115.
[91] Ethicon's Seven Year Dog Study (ETH.MESH.09888189) pg.117.

be masked by the strong carbonyl absorbances normally observed for these sutures."[90] Thus, no conclusions could be drawn from the IR microscopy of any of the examined explanted sutures.

Direct molecular weight measurements via GPC were performed on both unimplanted controls and PROLENE sutures after seven years *in vivo* to determine if a shift in molecular weight had occurred. It is worth mentioning that direct measurements of molecular weight reduction are the most accurate and reliable method to assess degradation in polymeric materials. Results (shown in Table 1) indicated that "there was no significant difference in molecular weight between the 4-0 PROLENE control and the seven year explant."[90] The findings from this study are clear. Within the margins of statistical error, none of the implanted sutures suffered any meaningful losses in molecular weight and therefore, by definition, were not degraded.[92]

Table 1. Molecular weight of exemplar PROLENE compared to explanted PROLENE sutures after 7 years *in vivo*.[72]

	M_w	M_n	PDI
Exemplar	324,000	60,000	4.67
Dog # 2007 site 1	322,000	69,000	5.13
Dog # 2007 site 6	323,000	63,000	5.54
Dog # 1995 site 3	327,000	59,000	5.17
Dog # 2019 site 3	331,000	64,000	5.82
Dog # 2019 site 2	332,000	57,000	6.08

Inherent viscosity tests of ETHILON and Novafil sutures were performed on samples from the seven year study period and compared to data from one and two year samples. The inherent viscosity of a polymer is directly related to its molecular weight. Obtained data showed no change in inherent viscosity in either type of suture after 1-2 years *in vivo* residence. However, after seven years the values ranged from 75% to 93% of those in the one and two year study period for the ETHILON sutures and 75% to 90% for the Novafil sutures.[93]

[92] This observation is also significant because it directly contradicts inferences by Plaintiff's experts that low molecular weight degradation materials from PROLENE are leaching into adjacent tissue.

[93] Ethicon's Seven Year Dog Study (ETH.MESH.09888188) pg.116.

A polymer's mechanical properties are directly influenced by its molecular weight. When a polymer experiences chemical degradation, including oxidation, its polymer chains are cleaved and reductions in molecular weight are realized. From a bulk physical property standpoint, chemical degradation/molecular weight loss generally results in embrittlement of the material. Embrittlement is best described as a decrease in a material's elongation-at-break, ductility or toughness (area under the stress-strain curve) meaning that the material's ability to stretch, prior to fracturing, has been reduced (Figure 7). Quantifiable changes or shifts in a material's ductility due to degradation are easily computed by performing tensile tests on control and degraded specimens.

In contrast, a polymer's ductility and toughness can increase as a result of plasticization. Plasticization of polymers is well documented in the scientific literature and occurs when low molecular weight compounds diffuse from an external source into the bulk polymer and physically change the intermolecular forces between polymer chains.[94] Specifically, plasticization of a polymer will result in a decreased modulus, increased elongation at break, and decreased breaking strength. Of equal importance is that plasticization is not a chemical degradation mechanism and does not, itself, result in a reduction of molecular weight.

[94] Wypych, G. *Handbook of Plasticizers*. Burlington: Elsevier Science, 2013.

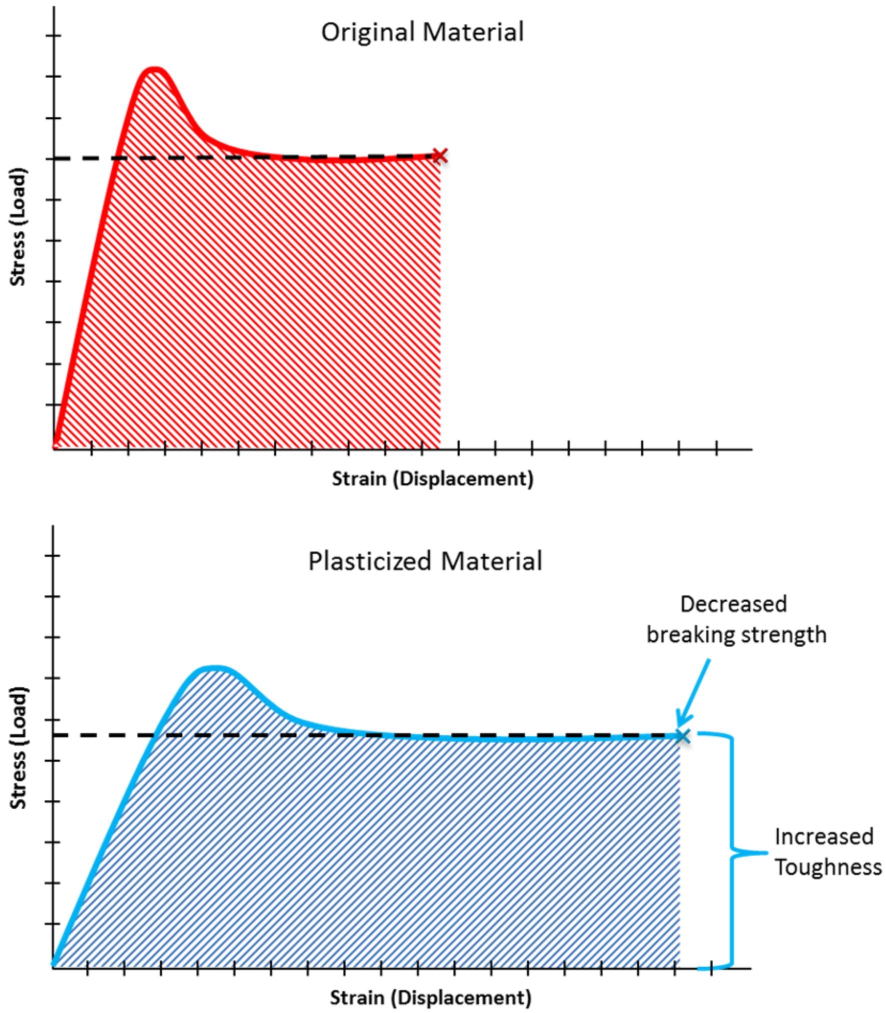

Figure 7. Schematic stress-strain curves for a non-plasticized and a plasticized material. Note the increase in toughness (area under the stress-strain curves) due to plasticization.

In addition to the molecular weight analysis, Ethicon evaluated the mechanical properties of explanted sutures from the seven year dog study to further determine if the bulk physical properties of the PROLENE material were being degraded during implantation. Tensile testing of sutures was performed on both pristine unimplanted and explanted sutures to evaluate the effect of implantation time on the mechanical properties of the suture material. The resulting breaking strength, elongation at break, and Young's modulus are summarized graphically in Figure 8. These tests revealed that ETHILON and Novafil sutures exhibited the greatest decrease in breaking strength, with a 37% and 14% decrease respectively.[95] Furthermore, the

[95] Ethicon's Seven Year Dog Study (ETH.MESH.11336183) pg.155.

physical appearance of the ETHILON sutures was reported as "fragile and worn out with spotted surface."[96] Conversely, "no significant change after seven year (sic) of implantation"[96] in breaking strength was reported for both PROLENE and PVDF sutures.

The elongation at break reported for all explanted suture types increased after seven years and can be seen in Figure 8. The most dramatic elongation *increase* was reported in PROLENE samples, which exhibited a 111% increase over pristine, non-implanted control samples.[95] A dramatic increase in ductility, in conjunction with a reduction in modulus (stiffness) is not indicative of degradation or oxidation, but instead confirms the PROLENE material's ductility and toughness *improve* as a function of implantation time and the improvement is most likely attributed to *in vivo* plasticization.

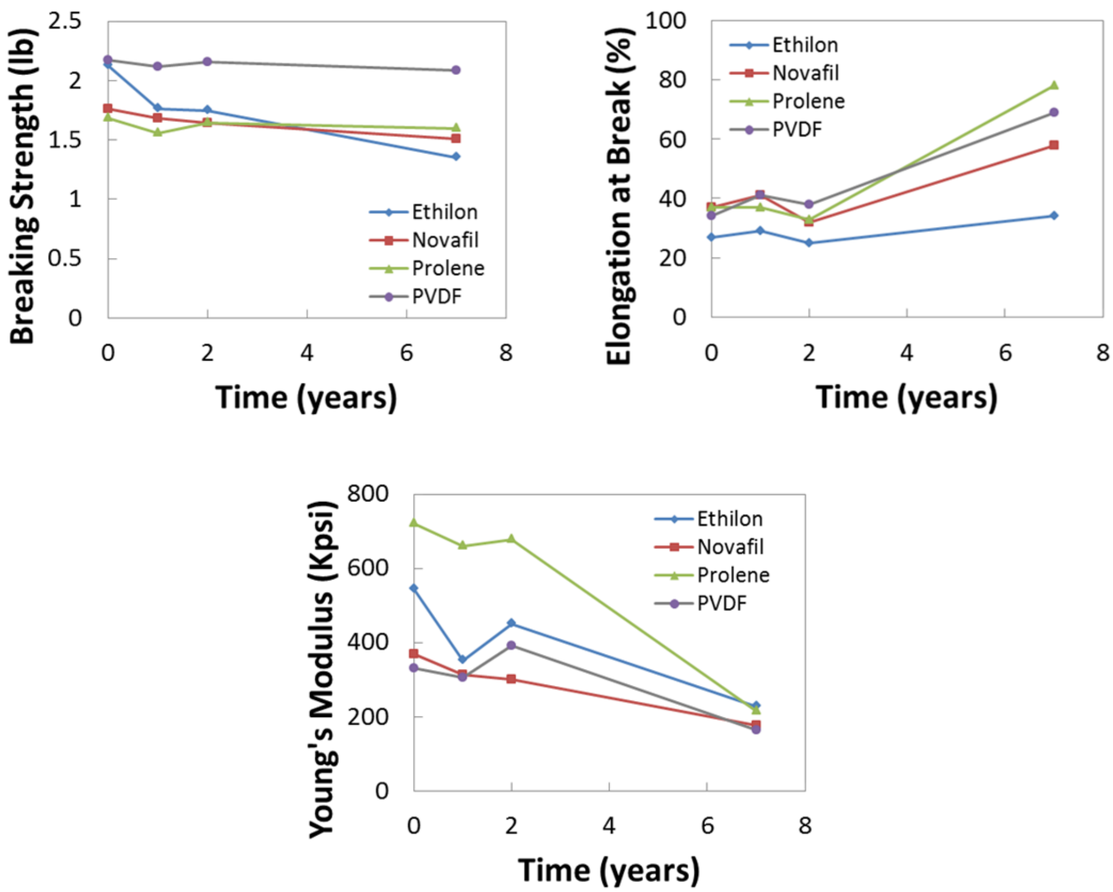

Figure 8. Summary of tensile tests performed on ETHILON, Novafil, PROLENE and PVDF sutures in Ethicon's Seven Year Dog Study.

[96] Ethicon's Seven Year Dog Study (ETH.MESH.11336181) pg.153.

Surface examinations of one suture of each type from each site were performed using both OM and SEM. Microcracking and/or damage was observed on the surface of the sutures as summarized in Table 2. Cracking was considered the most severe and widespread on ETHILON sutures, and was observed after one year *in vivo*. The presence of cracks on explanted Novafil sutures did not follow a clear trend, as seen in Table 2. After seven years *in vivo*, transverse cracking was not observed to a high degree on the Novafil sutures, although other signs of surface damage such as longitudinal scratches and a longitudinal crack were observed.[93] Transverse cracking was not observed on the surface of PROLENE sutures after one year *in vivo;* however*,* after seven years the appearance of cracking was reported on the surface of 50% of the sutures. Throughout the seven year study, only one of the PVDF explanted sutures was reported to have "possible cracks" on the surface.[97]

Table 2. Summary of suture surface examinations. The number of sutures exhibiting damage (transverse cracking, longitudinal cracking, scratches, etc.) and the total number of sutures of each type after one, two, five and seven years *in vivo*.

	1 year[97]	**2 years[97]**	**5 years[98]**	**7 years[99]**
PROLENE	0 of 8	1 of 8	2* of 7	4 of 8
PVDF	0 of 8	1 of 8	0 of 7	1 of 7
ETHILON	7 of 7	5 of 7	8 of 8	8 of 8
Novafil	4 of 7	2 of 7	0 of 8	4 of 7

* One additional suture revealed cracking only after drying.

Conclusion

Overall, Ethicon invested substantial resources in their multi-year investigation into the composition of the cracked outer layer observed on explanted PROLENE sutures. Ethicon's Seven Year Dog Study data strongly confirms that PROLENE is not experiencing any meaningful degradation *in vivo*, in fact, the material exhibits more ductility and rupture resistance after long-term implantation.

[97] Ethicon's Seven Year Dog Study (ETH.MESH.11336081 – 11336082) pg.92-93.

[98] Ethicon's Seven Year Dog Study (ETH.MESH.11336165-11336168) pg.101-104.

[99] Ethicon's Seven Year Dog Study (ETH.MESH.09888191) pg.119.

- Dr. Iakovlev has not performed any control experiments nor cited any scientific studies that support his belief that degraded PROLENE is capable of being histologically stained with H&E stains, and for these reasons, his conclusions are flawed and suspect.

- Through a series of controlled oxidation, microtoming, and microscopy experiments, Exponent demonstrated that oxidized PROLENE meshes do not become stained with H&E dyes. This fact is supported by polymer science first principles, given that PROLENE does not possess chemical groups amenable to binding with the H&E stain molecules.

- Artifacts can be easily introduced during sample preparation, sectioning, staining, and imaging, giving the appearance of darkened outer layers.

- A brittle outer layer will not contribute to the stiffness of the mesh if it is thin, cracked, and discontinuous. Dr. Iakovlev's opinion that a thin, cracked, porous outer layer causes an increase in mesh stiffness is not consistent with first principles of polymer science and solid mechanics.

If you have any questions or require additional information, please do not hesitate to contact me.

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